

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Eugenio Cefali, et al.
Serial No.: 08/960,557
Filing Date: 31 October 1997
Docket Number: 50454-56103USCIP
Title: METHODS FOR TREATING HYPERLIPIDEMIA WITH
 INTERMEDIATE RELEASE NICOTINIC ACID COMPOSITIONS
 HAVING UNIQUE BIOPHARMACEUTICAL CHARACTERISTICS
Art Unit: 1615
Examiner: J.M. Spear
Date: 4 January 2005

Mail Stop 313(c)
 Commissioner for Patents
 P.O. Box 1450
 Alexandria, VA 22313-1450

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SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Sir:

In compliance with the duty of disclosure under 37 C.F.R. § 1.56 and in accordance with the practice under 37 C.F.R. §§ 1.97 and 1.98, the Examiner's attention is directed to the documents listed on the enclosed Form PTO-1449. Copies of the listed documents are also enclosed.

REMARKS

The cited documents include experts reports exchanged in the pending litigation involving Kos Pharmaceuticals, Inc. and Barr Laboratories, Inc. ("Consolidated Case No. 02 CV 1683"), and articles and documents cited in those reports to the extent that they have not yet been considered by the Examiner. To the extent the cited documents are subject to the protective order in Consolidated Case No. 02 CV 1683, they are being submitted for consideration under MPEP § 724. In addition, to the extent the cited documents contain information confidential to Barr Laboratories, Inc. and to any third parties to Consolidated Case No. 02 CV 1683, they are being submitted in redacted form.

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FORMAL MATTERS

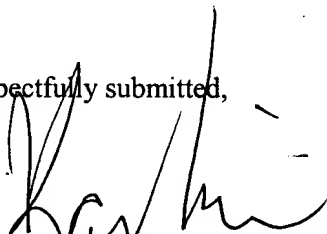
Any fee required in connection with this paper should be charged to Deposit Account 50-2543. A duplicate of this paper is enclosed.

CONCLUSION

It is respectfully requested that the above information be considered by the Examiner and that a copy of the enclosed Form PTO-1449 be returned indicating that such information has been considered.

Applicants' undersigned attorney may be reached at (954) 331-3825. All correspondence should continue to be directed to our below listed address.

Respectfully submitted,



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Date: 1/4/05

FORM PTO 1449 (modified)			ATTY DOCKET NO. 5045-56103USCIP			APPLICATION NO. 08/960,577		
U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE			APPLICANT Eugenio Cefali, et al.					
LIST OF REFERENCES CITED BY APPLICANT(S) (Use several sheets if necessary)			FILING DATE 31 October 1997				GROUP 1615	
U.S. PATENT DOCUMENTS								
*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE	
FOREIGN PATENT DOCUMENTS								
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES/NO/ OR ABSTRACT	
OTHER DOCUMENT(S) (Including Author, Title, Date, Pertinent Pages, Etc.)								
DOCUMENTS SUBMITTED UNDER MPEP § 724								
		Expert Report of Cheryl D. Blume, Ph.D. (January 27, 2004) - Subject to Protective Order						
		Expert Report of Dr. Sergio Fazio (February 4, 2004) [Redacted Version] - Subject to Protective Order						
		Rebuttal Expert Report of Dr. Sergio Fazio (April 2, 2004) - Subject to Protective Order						
		Expert Report of Dr. Sergio Fazio Regarding U.S. Patent No. 6,676,967 (August 17, 2004) - Subject to Protective Order						
		Expert Report of Don W. Martens (February 6, 2004) [Redacted Version] - Subject to Protective Order						
		Expert Report of Don W. Martens Regarding U.S. Patent No. 6,676,967 (August 20, 2004) [Redacted Version] - Subject to Protective Order						
		Expert Report of Dr. Joseph R. Robinson (February 5, 2004) [Redacted Version] - Subject to Protective Order						
		Expert Report of Dr. Joseph R. Robinson Regarding U.S. Patent No. 6,676,967 (August 18, 2004) - Subject to Protective Order						
EXAMINER				DATE CONSIDERED				

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered.
Include copy of this form with next communication to applicant.

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	Rebuttal Expert Report of Thomas S. Foster, Pharm.D. (April 2, 2004) - Subject to Protective Order	
	Rebuttal Expert Report of Thomas S. Foster, Pharm.D. Regarding The '967 Patent (October 4, 2004) - Subject to Protective Order	
	Rebuttal Expert Report of James W. McGinity, Ph.D. (April 2, 2004) - Subject to Protective Order	
	Supplemental Rebuttal Expert Report of James W. McGinity, Ph.D. (August 18, 2004) - Subject to Protective Order	
	Rebuttal Expert Report of James W. McGinity, Ph.D. Regarding The '967 Patent (September 30, 2004) - Subject to Protective Order	
	Expert Report of Mark E. McGovern, M.D. (February 6, 2004) - Subject to Protective Order	
	Expert Report of Mark E. McGovern, M.D. (August 20, 2004) - Subject to Protective Order	
	Expert Report of Frank M. Sacks, M.D. (April 2, 2004) - Subject to Protective Order	
	Expert Report of Frank M. Sacks, M.D. (August 20, 2004) - Subject to Protective Order	
	Rebuttal Expert Report of Mary Ann Tucker, Esq. (April 2, 2004) - Subject to Protective Order	
	Rebuttal Expert Report of Mary Ann Tucker, Esq. Regarding The '967 Patent (October 1, 2004) - Subject to Protective Order	

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DOCUMENTS SUBMITTED UNDER MPEP § 724			
		Sample Kos Clinical Trial Medical Consent Form - Subject to Protective Order	
		Sample Kos Clinical Trial Investigator's Statement - Subject to Protective Order	
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	Carl J. Lavie, et al., <i>Marked Benefit with Sustained-Release Niacin Therapy in Patients with "Isolated" Very Low Levels of High-Density Lipoprotein Cholesterol and Coronary Artery Disease</i>, Am. J. Cardiol. 1992:69:1083-1085	
	Excerpts from the 1993, 2000 and 2002 editions of the Physician's Desk Reference 1993 edition (pp. 434, 611, 856, 1189, 1919, 1920, 2491 and 2492) 2000 edition (pp. 1519-1523) 2002 edition (pp. 1846-1850)	
	<i>Niacin: Double-edged Sword for Lowering Cholesterol</i>, Tufts University Diet & Nutritional Letter (Tufts Univ., Boston, MA), August 1994, Vol. 12, issue 6	
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	Lavie, Letter to Editor, JAMA 1994; 272:513-515	
	Keenan, Letter to Editor, JAMA 1994; 272:513-515	
	Shields & Beckmann, Letter to Editor, JAMA 1994; 272:513-515	
	Thomas N. Tozer, <i>Clinical Pharmacokinetics Concepts and Applications</i> (3d ed. 1995) at Chapter 9, p. 120	
	Excerpts from the 1995 United States Pharmacopeia (pp. iii-vi, 1080-1082, 1793-1799, 1940-1944)	
	Morgan & Capuzzi Abstract, <i>Safe and Effective Treatment of Dyslipidemia by Niaspan, a New Sustained-Release Niacin</i>, Clinical Pharmacology & Therapeutics (February 1996)	
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	Knopp RH, et al., <i>Equivalent Efficacy of a Time-Release Form of Niacin (Niaspan) Given Once-a-Night Versus Plain Niacin in the Management of Hyperlipidemia</i>, Metabolism 47:1097-1104 (1998)		
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	Elam MB, et al., <i>Effect of Niacin on Lipid and Lipoprotein Levels and Glycemic Control in Patients With Diabetes and Peripheral Arterial Disease</i>, JAMA: 2000; 284:1263-1270		
	Kesala R, et al., <i>Niacin (N) vs. Niaspan (NS) Treatment of the Atherogenic Lipid Profile (ALP; Small, Dense LDL, HDL2, HDLc and Triglycerides) and Lp(a) in Diabetic Patients (DP)</i>, Diabetes 49 (suppl. 1): A268 at 1114-P (June 2000)		
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	Meadows M., <i>Serious Liver Injury: Leading Reason for Drug Removals, Restrictions</i>, FDA Consumer Magazine, May-June 2001; http://www.fda.gov/fdac/features/2001/301_liver.html		
	Grundy SM, et al., <i>Efficacy, Safety, and Tolerability of Once-Daily Niacin for the Treatment of Dyslipidemia Associated with Type 2 Diabetes</i>. Arch Intern Med. 2002; 162: 1568-1576		
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	Meyers CD, et al., <i>Varying Cost and Free Nicotinic Acid Content in Over-the-Counter Niacin Preparations for Dyslipidemia</i>, Ann Intern Med. 2003; 139:996-1002		
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Form #62